Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine to Persons 12 Years of Age and Older

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess persons 12 years of age and older for vaccination with Pfizer BioNTech COVID-19 Vaccine based on the following criteria:

- Primary-series vaccination
  - If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, administer the second dose at an interval of least 21 days.[†]
  - If the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.
  - If 2 doses of an mRNA vaccine have been administered or a single dose of Janssen COVID-19 Vaccine has been administered, the person is considered fully vaccinated 14 days after completing the primary vaccination series. Those receiving a 2-dose mRNA series may need an additional dose (moderately to severely immunocompromised persons) at least 28 days after completing a two-dose series or a booster dose (at least 6 months after completing a primary mRNA series). All persons who received a single dose Janssen COVID-19 Vaccine should get a booster dose of a COVID-19 vaccine at least 2 months (8 weeks) after receiving the primary dose.
- Persons with a history of myocarditis or pericarditis:
  - If history is prior to COVID-19 vaccination may receive any FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved
  - If myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, defer the second dose of an mRNA COVID-19 vaccine. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions
- Persons who are moderately to severely immune compromised[*]
  - For a person aged 18 years and older who received an mRNA vaccine: Consider an additional vaccine dose at least 28 days after an initial 2-dose primary series. Administer the same vaccine product as for the initial 2-dose primary series. If the vaccine product cannot be determined or is no longer available, administer either mRNA COVID-19 product.
  - For a person aged 18 years and older who received a primary dose of Janssen COVID-19 Vaccine: Consider a booster dose at least 2 months (8 weeks) after completing the initial dose. The booster dose may be any FDA-authorized or approved vaccine product.
- Persons who have received HCT or CAR-T-cell therapy
  - Revaccinate persons who received doses of COVID-19 vaccine prior to receiving HCT or CAR-T-cell therapy should be revaccinated with a primary series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.
- Booster doses
  - Administer a booster dose at least 6 months after completion of the Pfizer-BioNTech vaccine primary series to:
    - » People aged 65 years and older
    - » Residents aged 18 years and older in long-term care settings
    - » People aged 50-64 with underlying medical conditions (https://www.cdc.gov/coronavirus/2019-ncov/needextra-precautions/people-with-medical-conditions.html)
  - Administer a booster dose, based on individual benefits and risks, at least 6 months after completion of a Pfizer-BioNTech primary series to:
    - » People aged 18-49 years with underlying medical conditions https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions/html
    - » People aged 18-64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting https://cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html#Know
    - » People who are moderately to severely immunocompromised who have received 3 doses of an mRNA vaccine may consider receiving a booster dose with any COVID-19 vaccine at least 6 calendar months after their 3rd dose.
    - » Use of heterologous booster doses is allowed.
    - » Inform recipients, especially males 12 through 29 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination.[‡]
    - » For people who received a COVID-19 vaccine that is not currently authorized or approved in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines
    - » Pfizer-BioNTech COVID-19 vaccine may be coadministered with other vaccines without regard to timing, including simultaneous administration.[§]
    - » For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination

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- **Screen for contraindications and precautions**
  - **Contraindications:**
    - » Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
    - » Immediate allergic reaction[¶] of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine (see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C for a list of vaccine components)

      Note: Persons who have a contraindication to the mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 Vaccine (see footnote).[#] Prior to administration of Janssen COVID-19 Vaccine, inform:
      - Women 18-49 years of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group.[**]
      - People with a history of Guillain-Barré Syndrome of the possible increased risk for GBS.
      - These persons can receive any FDA-authorized or approved COVID-19 vaccine.
  - **Precautions:**
    - » Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
    - » History of an immediate allergic reaction[¶] of any severity to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
      - This includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is polyethylene glycol (PEG) or another vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
    - » People with a contraindication to Janssen COVID-19 Vaccine have a precaution to both mRNA vaccines (see footnote)[#]
    - » Moderate to severe acute illness

[*] For a list of conditions associated with moderate to severe immune compromise, see: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-additional-vaccine-dose

[†] If the second dose is administered less than 17 days after the first dose (4-day grace period), the dose should be repeated. The repeat dose should be spaced at least 21 days after the improperly administered Pfizer-BioNTech dose.

[‡] Educational materials are available at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

[§] When deciding whether to coadminister COVID-19 vaccine and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines., They should also consider the patient's risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

[¶] An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

[#] Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

[**] Educational materials are available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site[†]
Female or male fewer than 130 lbs	22–25	⅝[§] –1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 152–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

[†] Alternately, the anterolateral thigh can be used. A 1.5-inch needle may be used if administering vaccine in this site.

[§] Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

- Provide all recipients and/or parents/legal guardians with a copy of the current Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine. Choose the correct needle gauge, needle length, and injection site for persons:
  - 12 through 18 years of age:
    - » Needle gauge/length: 22-25 gauge, 1-inch
    - » Site: Deltoid muscle of arm.
  - 19 years of age and older: See chart above.
  - Mix Pfizer-BioNTech COVID-19 Vaccine with 0.9% sodium chloride (normal saline, preservative-free) diluent according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine.
- Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection.

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- Document vaccination.
  - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
  - Document each recipient's vaccine administration information:
    - » Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - » Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
    - » Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.
- Additional preparation and administration information is available on the manufacturer's website at www.cvdvaccine.com.
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - » **30 minutes:** Persons with a:
      - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
      - Contraindication to Janssen COVID-19 Vaccine who receive Pfizer-BioNTech Vaccine
      - History of anaphylaxis due to any cause
    - » **15 minutes:** All other persons
  - Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.
  - Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
  - Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.
  - For more information, please see:
    - » **Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html**
    - » **CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html**
    - » **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf**
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA), healthcare professionals are required to report to VAERS:
    - » Vaccine administration errors (whether associated with an adverse event [AE] or not)
    - » Serious AEs (irrespective of attribution to vaccination)
    - » Multisystem inflammatory syndrome (MIS) in adults or children
    - » Cases of COVID-19 that result in hospitalization or death
    - » Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
  - Healthcare professionals are encouraged to report to VAERS:
    - » Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the Kansas Local Health Departments

effective 11/05/2021 until rescinded or until 11/04/2022.

Medical director (or other authorized practitioner)

Lee A. Norman MD / _____.

Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders